Group IV: drawn to a method of using a modular microchannel apparatus (claims 22-24).

An election of the claims of Group I was made with traverse. In addition, new claims 26 and 27 were submitted. The Examiner made the restriction requirement final and entered claim 26. Claim 27 was withdrawn from consideration as being directed to a non-elected invention. Thus, claims 1-12, 25 and 26 are now pending.

The prior grounds of rejection have been withdrawn, and the following new rejections have been issued, as follows:

Claims 1-12, 25 and 26 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a disclosure that is not enabling;

Claims 1-4, 6, 7 and 25 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,571,410 to Swedberg et al. in view of U.S. Patent No. 4,654,127 to Baker et al.;

Claims 5, 8, 9 and 26 stand rejected under 35 U.S.C. §103(a) as obvious over Swedberg et al. in view of Baker et al. and U.S. Patent No. 5,968,331 to Kambara et al.; and

Claims 10-12 stand rejected under 35 U.S.C. §103(a) as obvious over Swedberg et al. in view of Baker et al., Kambara et al., and U.S. Patent No. 5,641,440 to Kaltenbach et al.

While U.S. Patent No. 5,128,104 to Murphy et al. is cited as art of interest, no rejection was made based on this patent.

The rejections are addressed in part by the above amendments to the claims and are otherwise traversed for reasons which will be discussed in detail below.

THE ABOVE AMENDMENTS:

Claims 1 and 25 have been amended to clarify that the separation unit is supplied with liquid reagents and analyte upon application of a driving force resulting from simultaneous operative and modular coupling. Support for these amendments is found, e.g., on page 10, line 14 to page 11, line 17. As the amendments are supported by the original disclosure, no new matter has been added.

THE REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH:

Claims 1-12, 25 and 26 were rejected under 35 U.S.C. § 112, first paragraph, for reasons of enablement. Specifically, the Examiner has asserted that a probe means for introducing the liquid reagent from the reservoir unit into the separation unit is critical or essential to the practice of the invention. In support of this assertion, the Examiner selectively pointed to FIG. 1, which is purported to illustrate that probes are used to apply a driving force to the liquid reagent and analyte from the reservoir unit through the microchannel of the separation unit.

Applicants point out that FIG. 1 represents only one way in which liquid reagent from the reservoir unit can be introduced into the separation unit. For example, the specification discloses that prior to coupling with a separation unit, a cover sheet of the reservoir unit may be peeled off in order to introduce reagent into the separation unit during coupling. *See, e.g.*, page 10, line 14 to page 11, line 10. In addition, it is disclosed that the reservoir may have a bottom which is thin so that it can be punctured by a protrusion arm from the separation unit to allow fluid flow from the reservoir into the separation unit. *See* page 11, lines 11-15. It is evident, then, that while the probe means illustrated in FIG. 1 represent one possible method for introducing the liquid reagent from the reservoir into the separation unit, there are other ways in which liquid reagent may be introduced without use of probe means. Thus, contrary to the Examiner's assertion, the probe means is not an essential or critical element of the invention.

Moreover, as amended, the claims now recite that separation unit is supplied with liquid reagents and analyte upon application of a driving force resulting from simultaneous operative and modular coupling. There is clear support in the specification for the new terminology, as indicated above. It is clear, then, that all claims are enabled by the specification as filed, and rejection on this basis should be withdrawn.

Not supported

THE 35 U.S.C. §103(A) REJECTION OVER SWEDBERG ET AL. IN VIEW OF BAKER ET AL.:

Claims 1-4, 6, 7 and 25 have been rejected as obvious over Swedberg et al. in view of Baker et al., newly cited. The Examiner has cited Swedberg et al. as disclosing a separation unit including a microchannel and a reservoir unit for coupling operatively and modularly with the separation unit to supply liquid reagents thereto, specifically citing column 29, lines 47-56 of the reference. The Examiner further stated that Swedberg et al. does not explicitly state that the

reservoirs have prepackaged liquid reagents therein before the reservoir unit is coupled to the separation unit. However, the Examiner has now cited Baker et al. as teaching a separation unit having a microchannel, a reservoir unit having dimensions compatible with the separation unit to supply liquid reagents and analytes thereto, the reservoirs having prepackaged liquid reagent therein before the reservoir unit is coupled to the separation unit, and membranes covering the reservoirs. The Examiner has asserted that it would have been obvious to one skilled in the art at the time of the invention to include prepackaged liquid reagents in the apparatus of Swedberg et al. in order to avoid contaminating the reagents before introduction into the microchannel and to eliminate the need for handling of calibrated reagents.

As an initial matter, applicant respectfully disagrees with the Examiner's characterization of Baker et al. as teaching a **separation unit**. Baker et al. is directed to a device for clinical chemistry and not to a separation unit *per se*. In fact, the word "separation" never appears in Baker et al. In addition, independent claim 1 as amended is drawn toward a modular microchannel apparatus for analysis of an analyte, comprising a separation unit and a reservoir unit having one or more reservoirs having prepackaged liquid reagents therein before the reservoir unit is coupled with the separation unit. **Upon application of a driving force resulting from simultaneous operative and modular coupling**, the reservoir unit supplies liquid reagents to the separation unit. Independent claim 25 is similarly amended.

To establish *prima facie* obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine reference teachings. Second, there must be a reasonable expectation of success and third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on an applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In this instance, the three criteria have not been met.

The first criterion has not been met because the Examiner has erroneously characterized that Baker et al. as disclosing a separation device. As discussed above, Baker et al. makes no disclosure with respect to separation at all. Thus, it appears that the Examiner employed improper hindsight analysis in issuing this rejection because there is no reason as to why a reference relating to a device for clinical chemistry would be read in combination with a reference describing a separation device, **without knowledge of applicant's invention**. Moreover, a prior art reference must be considered in its entirety, **i.e., as a whole**, including portions that would lead away from the claimed invention. *W.L.Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Baker et al. discloses on column 3, lines 22-32 that a prepackaged amount of calibrant fluid is transported through a capillary passage to calibrate an analyzer before the calibrant fluid is purged from the capillary by a sample fluid. Sequential introduction of different fluids suggests that separation is not needed, thereby teaching away from separation. Thus, one of ordinary skill in the art would not be motivated to combine Swedberg et al. with Baker et al.

Moreover, neither Swedberg et al. nor Baker et al. discloses **simultaneous operative and modular coupling that results in a driving force** that allows fluid to flow from a reservoir containing prepackaged liquid reagents to a separation unit. As stated by the Examiner, Swedberg et al. does not explicitly state that the reservoirs have prepackaged liquid reagents therein before the reservoir unit is coupled to the separation unit. In addition, Baker et al. is directed to a device that employs an action distinct from a driving force resulting from simultaneous operative and modular coupling, e.g., turning to a "start position" as disclosed in column 9, lines 47-52, in order to allow fluid to flow from the reservoir. For example, Baker et al. discloses that a cylindrical reservoir is mounted within a sleeve of an analytical unit and **then** rotated. *See* column 4, line 38 to column 5, line 50. Thus, Baker discloses a device that allows for fluid flow **without** simultaneous operative and modular coupling, and the third criteria also fails as neither reference discloses each and every element of the claim.

For the above reasons, *prima facie* obviousness has not been established and the rejection is in error. Reconsideration and withdrawal of the rejection is accordingly respectfully requested.

THE REJECTION UNDER 35 U.S.C. §103(A) OVER SWEDBERG ET AL. IN VIEW OF BAKER ET AL. AND KAMBARA ET AL.:

Claims 5, 8 and 9 have been rejected as obvious over Swedberg et al. in view of Baker et al. and Kambara et al., also newly cited. The Examiner has cited Swedberg et al. and Baker et al. as before and acknowledged that neither Swedberg et al. nor Baker et al. teach an apparatus wherein the membranes are penetrable with a probe, the probe being used for applying a driving force to drive movement of the liquid reagent and analyte from the reservoir through the microchannel. However, the Examiner cited Kambara et al. as teaching a reservoir unit containing a liquid and being penetrable with probes used for applying a force to drive chemicals from the reservoir through the microchannel, specifically citing column 8, lines 4-40, of the reference. The Examiner therefore contends that it is obvious to include in the apparatus of Swedberg et al. and Baker et al. probes to drive liquid into microchannels in order to reduce the time and labor needed to introduce the liquids in the microchannels.

As before, applicant respectfully disagrees. The rejected claims all depend from independent claim 1 which, as discussed above, is nonobvious over Swedberg et al. and Baker et al. as neither patent teaches that a driving force may result from simultaneous modular and operative coupling. The addition of Kambara et al. does not **provide any further teaching or suggestion of such a driving force resulting from simultaneous modular and operative coupling and therefore provides no additional basis for the rejection of the independent claim**. In fact, Kambara et al. is directed to a sample injecting device for an electrophoresis apparatus, wherein an electric field is applied to inject the sample electrophoretically into the gel in an electrophoresis separation capillary. As disclosed in column 8, lines 34-40 of Kambara et al., the electric field is not applied until after the device is assembled. Thus, this patent also teaches away from simultaneous modular and operative coupling to provide a driving force to supply liquid reagents and analyte.

As the references in combination fail to disclose each and every element of the claims, they represent an improper basis for a §103(a) rejection. Reconsideration and withdrawal of the rejection is thus requested.

THE REJECTION UNDER 35 U.S.C. §103(A) OVER SWEDBERG ET AL. IN VIEW OF BAKER ET AL., KAMBARA ET AL. AND KALTENBACH ET AL.:

Claims 10-12 were rejected as obvious over Swedberg et al. in view of Baker et al., Kambara et al. and Kaltenbach et al., the Examiner citing Swedberg et al., Baker et al. and Kambara et al. as before and stating that the addition of the peltier plate recited in these claims would have been obvious to one skilled in the art given the teaching of Kaltenbach et al. As before, applicant disagrees. The rejected claims depend from independent claim 1 which is nonobvious over Swedberg et al., Baker et al. and Kambara et al. for the reasons discussed above. **The addition of Kaltenbach et al. does not provide any further teaching or suggestion of such simultaneous modular and operative coupling and therefore provides no additional basis for the rejection of the independent claim.** As the rejected claims all depend from a non-obvious claim, they too are nonobvious. Reconsideration and withdrawal of the rejection is thus requested.

CONCLUSION

For all of the above reasons, it is submitted that the application comports with all requirements of 35 U.S.C. §112, and that the pending claims define an invention that is patentable over the art. As the application is now in condition for allowance, a prompt indication to that effect would be appreciated. Should the Examiner have any questions concerning this communication, he is welcome to contact the undersigned attorney at (650)851-8501.

Respectfully submitted,

8/1/2000
Date

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